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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/166,701	10/05/1998	ISA ODIDI	SMI-005.01	9432

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EXAMINER

WEBMAN, EDWARD J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/06/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/166701

Applicant(s)

ODIDJ

Examiner

W. F. MAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 2/14/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 4, 7-12, 23, 28-33 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 4, 7-12, 23, 28-33 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 7-12, 23, 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guley et al in view of Jain et al.

Guley et al teach a controlled release (tablet) core comprising 20-70% drug and a 20-72% mixture of water soluble and water-insoluble polymers at a ratio of 10:1-1.5:1 (column 2 lines 27-36). Hydroxypropyl cellulose and carboxyl vinyl polymer are specified (column 2 lines 42 and 48-49). A coating comprising cellulose acetate phthalate is disclosed (column 3 line 19). Etodolac is specified (column 4 line 67). Lactose is disclosed (column 5 example 1). Sustained release is specified (Title). Excipients, including lubricants, are disclosed (column 3 lines 3-6). Talc and calcium st^earate are specified (example 1 column 5). Guley et al further teach plural water soluble polymers including hydroxypropyl methyl cellulose and hydroxy propyl cellulose (column 2 lines 40-44). Plural water-insoluble polymers are specified including ethyl cellulose and carboxyl vinyl polymer (column 2 lines 45-50).

Jain et al teach the equivalence of cellulose alkyl hydroxylates in (tablet) cores, in particular that of hydroxypropyl cellulose and hydroxyl ethyl cellulose (column 5 lines 21-27).

It would have been obvious to one of ordinary skill to make a core comprising a carboxyl vinyl polymer, and alkyl cellulose in view of Guley et al. As to the claimed

Art Unit: 1617

hydroxy ethyl cellulose, Jain et al teach the equivalence of this hydroxypropyl cellulose of Guley et al in tablet cores.

As to the claimed magnesium stearate, Jain et al teach magnesium stearate as a ²tableting lubricant (column 7 lines 44-45). It would have been obvious to add magnesium stearate to the composition of Guley et al as an additional lubricant in view of Jain et al.

Applicants cite tables and a figure demonstrating the non-equivalence of hydroxypropyl cellulose and hydroxyethyl cellulose. However, the tables and figure are not of record.

Claims 9, 30 are objected to because of the following informalities: claims 9, 30 contain the trademark "CARBAPOL". Appropriate correction is required.

Claims 9, 30 contain the trademark/trade name CARBAPOL. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a polymer and, accordingly, the identification/description is indefinite.

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 305-3592 for regular communications and 305-1235 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234.

Application/Control Number: 09/166,701

Page 5

Art Unit: 1617

Webman/tgd

May 20, 2003


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